

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, ex rel.	:	
ANTHONY R. SPAY,	:	
	:	CIVIL ACTION
Plaintiff,	:	
	:	
v.	:	NO. 09-4672
	:	
CVS CAREMARK CORPORATION;	:	
CAREMARK Rx, LLC (f/k/a CAREMARK	:	
Rx, Inc.); CAREMARK, LLC (f/k/a	:	
CAREMARK, INC.); SILVERSCRIPT, LLC	:	
(f/k/a SILVERSCRIPT INC.),	:	
	:	
Defendants.	:	

**MEMORANDUM**

BUCKWALTER, S.J.

April 23, 2013

Currently pending before the Court is the Motion by Plaintiff/Relator Anthony R. Spay (“Plaintiff” or “Relator”) to Strike Defendants’ Affirmative Defenses. For the following reasons, the Motion is granted in part and denied in part.

**I. FACTUAL AND PROCEDURAL BACKGROUND**

The present litigation is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements, and claims made, used, and caused to be made, used, or presented by Defendants CVS Caremark Corporation, Caremark Rx, LLC (f/k/a Caremark Rx, Inc.), Caremark, LLC (f/k/a Caremark, Inc.), and Silverscript, LLC (f/k/a/ Silverscript, Inc.) (collectively “Defendants”). (Am. Compl. ¶

1.) At the core of the Amended Complaint, filed on August 5, 2011, is the allegation that

Defendants violated the False Claims Act, 31 U.S.C. § 3729, et seq. (“FCA”), in their roles as both a Pharmacy Benefit Manager (“PBM”) and a Sponsor of the Medicare Part D Prescription Drug Program (“Part D Sponsor”), by engaging in a nationwide practice of fraudulently adjudicating and submitting improper Prescription Drug Event (“PDE”) claims to the Center for Medicaid and Medicare Services (“CMS”) under the Part D Program. Plaintiff also alleges that Defendants violated the FCA by falsely certifying that the PDE data submitted to CMS was truthful, accurate and complete.

Following the filing of the Amended Complaint, Defendants moved to dismiss the Amended Complaint on a multitude of grounds. Upon thorough consideration of the parties’ extensive briefing, the Court issued a lengthy opinion denying the Motion in its entirety.<sup>1</sup> Thereafter, Defendants filed their Answer, together with thirty Affirmative Defenses, on February 1, 2013.

On February 21, 2013, Plaintiff filed the present Motion to Strike the First, Second, Third, Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, Eleventh, Twelfth, Fifteenth, Sixteenth, Seventeenth, Eighteenth, Twenty-Third, Twenty-Fifth, and Twenty-Eighth Affirmative Defenses. Defendants responded on March 19, 2013, and Plaintiff filed a Reply Brief on April 5, 2013. The matter is now ripe for judicial consideration.

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<sup>1</sup> In an effort to avoid repetition, the Court incorporates by reference the lengthy summary of the allegations in the Amended Complaint set forth in our Memorandum of December 20, 2012. U.S. ex rel. Spay v. CVS Caremark Corp., \_\_\_ F. Supp. 2d \_\_\_, 2012 WL 6645537 (E.D. Pa. Dec. 20, 2012).

## II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(f) permits a court to “strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). “An affirmative defense is insufficient if it is not recognized as a defense to the cause of action.” Total Containment, Inc. v. Environ Prods., Inc., No. Civ.A.91-7911, 1992 WL 208981, at \*1 (E.D. Pa. Aug. 19, 1992) (quotations omitted). Although a court has considerable discretion with motions to strike, as a general rule they are not favored and “usually will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.” River Road Devel. Corp. v. Carlson Corp., No. Civ.A.89-7037, 1990 WL 69085, at \*2 (E.D. Pa. May 23, 1990) (citing 5 C. Wright & A. Miller, Federal Practice and Procedure § 1382. 809-10, 815 (1969)). Striking a pleading is a “drastic remedy” and should be used sparingly by courts, partly because of the difficulty of deciding cases without a factual record. North Penn Transfer, Inc. v. Victaulic Co. of Am., 859 F. Supp. 154, 158–59 (E.D. Pa. 1994). The Third Circuit has cautioned that courts “should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’” Cipollone v. Liggett Grp., Inc., 789 F.2d 181, 188 (3d Cir. 1986); see also Linker v. Custom-Bilt Mach., 594 F. Supp. 894, 898 (E.D. Pa. 1984) (“An affirmative defense can be stricken ‘only if the defense asserted could not possibly prevent recovery under any pleaded set or inferable set of facts.’”). Thus, “[a] motion to strike will not be granted where the sufficiency of a defense depends on disputed issues of fact.” Id. (citations omitted). Even when facts are not in dispute, a motion to strike is not the appropriate procedure to determine disputed or unclear questions of law. Id.

### **III. DISCUSSION**

Via the present Motion, Plaintiff seeks dismissal of nineteen of Defendants' thirty Affirmative Defenses on one of three grounds. First, he asserts that the First, Second, Third, Tenth, and Eleventh Affirmative Defenses attempt to re-litigate issues which have already been decided by this Court in its December 20, 2012 Memorandum and Order. Second, he claims that the Twelfth, Twenty-Third, Twenty-Fifth, and Twenty-Eighth Affirmative Defendants are not available as a matter of law in claims brought on behalf of the United States Government. Finally, Plaintiff argues that the Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Fifteen, Sixteenth, Seventeenth, and Eighteenth Affirmative Defenses are not actually affirmative defenses, but rather mere denials of liability of the elements of Plaintiff's cause of action. Defendants, on the other hand, contend that the remainder of their Affirmative Defenses are valid and should not be stricken by the Court.<sup>2</sup> The Court now considers each of Plaintiff's challenges individually.

#### **A. Issues Already Decided by the Court**

Plaintiff initially argues that the First, Second, Third, Tenth, and Eleventh Affirmative Defenses were already adjudicated by the Court in the December 20, 2012 Memorandum and Order. Accordingly, he contends that the law of the case doctrine precludes reconsideration of these issues and requires that they be dismissed.

##### **1. First and Second Affirmative Defenses**

The First Affirmative Defense states that "The Amended Complaint and its purported causes of action fail to state facts sufficient to adequately plead a cause of action against

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<sup>2</sup> Defendants voluntarily withdrew both their Twenty-Fifth Affirmative Defense regarding mitigation of damages and the reference in their Twelfth Affirmative Defense to unclean hands. (Defs.' Resp. Opp'n Mot Strike 3 n.3 & 13 n.9.)

Defendants.” (Answer at Aff. Def. 1.) The Second Affirmative Defense asserts that, “The Amended Complaint and its purported causes of action fail to meet the pleading requirements of Federal Rules of Civil Procedure 8(a) and 9(b).” (Id. at Aff. Def. 2.) Plaintiff now contends that the Court expressly considered and rejected these precise affirmative defenses in denying Defendants’ Motion to Dismiss, meaning that they may not be re-litigated in this case.<sup>3</sup>

Federal Rule of Civil Procedure 12(b) provides that “[a] defense of failure to state a claim upon which relief can be granted may be made in any pleading permitted or ordered under Rule 7(a).” Fed. R. Civ. P. 12(b). Thus, “[t]he Federal Rules specifically permit an averment of failure to state a claim to be raised as an affirmative defense.” Cintron Beverage Grp., LLC v. Depersia, No. Civ.A.07-3043, 2008 WL 1776430, at \*2 (E.D. Pa. Apr. 15, 2008). “[I]t is well-settled that a party can set forth the defense of failure to state a claim as an affirmative defense in the answer.” Id. (citing Greiff v. T.I.C. Enter., LLC, No. Civ.A.03-842, 2004 WL 115553, at \*2 (D. Del. Jan. 9, 2004)); see also F.D.I.C. v. Modular Homes, Inc., 859 F. Supp. 117, 122 (D.N.J. 1994) (noting that “[s]ince there is a federal rule on point which recognizes that failure to state a claim upon which relief can be granted is a defense,” the defendant will be permitted to raise this defense).

Where, however, a court has previously made a legal determination that a Plaintiff’s complaint stated a claim for relief, a subsequent affirmative defense claiming failure to state a

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<sup>3</sup> “[T]he doctrine of the law of the case posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case.” Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 815–16 (1988) (citations and internal quotations omitted); see also In re Resyn Corp., 945 F.2d 1279, 1281 (3d Cir. 1991) (“The doctrine of the law of the case dictates ‘when a court decides upon a rule of law, that rule should continue to govern the same issues in subsequent stages in the litigation.’”) (quotations omitted).

claim or to properly plead should be stricken. Nupro Indus. Corp. v. Lexington Ins. Co., No. Civ.A.08-4809, 2010 WL 2553698, at \*3 (E.D. Pa. June 21, 2010); see also Trustees of Local 464A United Food & Comm. Workers Union Pension Fund v. Wachovia Bank, N.A., No. Civ.A.09-668, 2009 WL 4138516, at \*2 (D.N.J. Nov. 24, 2009) (“The Court made a legal determination that Plaintiffs’ complaint stated a claim for relief. Thus, Defendants are not permitted to reassert this argument, which the Court has already deemed insufficient, in the guise of an affirmative defense.”); In re Modern Creative Serv., Inc. v. Dell, Inc., No. Civ.A.08-3591, 2008 WL 305747, at \*3–4 (D.N.J. Jan. 28, 2008) (striking affirmative defenses already considered and rejected by the court on a motion to dismiss). Otherwise, defendants would have the opportunity to seek reconsideration of a court’s legal finding through the vehicle of an affirmative defense.

In the present case, Defendants’ previous Motion to Dismiss challenged almost every aspect of Plaintiff’s pleading Amended Complaint under the FCA. Applying Federal Rules of Civil Procedure 8, 9, and 12(b)(6) as interpreted by the United States Supreme Court, this Court found that Plaintiff had adequately stated a False Claims Act cause of action upon which relief can be granted. Their argument under this standard having already been rejected, Defendants are not entitled to another bite at the apple to reassert—simply in an alternative format—the identical theory.

Defendants’ efforts to resuscitate these Defenses are unavailing. First, Defendants contend that in the Motion to Dismiss the Court was required to accept as true all of Plaintiff’s factual allegations, while, at this point, Plaintiff’s facts are no longer deemed true and Plaintiff bears the burden of showing that the defense asserted could not possibly prevent recovery under

any pleaded set or inferrable set of facts. This argument, however, merely creates a distinction without a difference. Even pursuant to its Affirmative Defenses, Defendants still must establish that the Amended Complaint, taken as true, fails to state a claim upon which relief may be granted under Federal Rule of Civil Procedure 12(b)(6) and the standards described in Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007) and Ashcroft v. Iqbal, 556 U.S. 662 (2009). As the Court has already ruled that Defendants cannot meet this standard, re-asserting this argument via an Affirmative Defense is futile. Nor is the previous Memorandum's use of language such as "at this early stage of the litigation" and "as this case progresses" suggestive that the ruling under 12(b)(6) was anything other than conclusive. As noted in an analogous case, "[t]he fact that this Court may have used language such as 'at this time' or 'at this stage of the litigation' in allowing such tort claims to proceed, was not done so as to give Defendant the ability to renew arguments which have been squarely addressed and decided by this Court as a matter of law. Rather, such language was used merely to reflect the fact that Plaintiff's ability to ultimately meet its burden of proof as to its various tort claims remains to be seen." Modern Creative Servs., 2008 WL 305747, at \*4.<sup>4</sup>

Likewise, Defendants' efforts to liken this Court's previous ruling in The Knit With v. Knitting Fever, Inc., No. Civ.A.08-4221, 2009 WL 973492 (E.D. Pa. Apr. 8, 2009) are meritless. In that case, the plaintiff argued that the defendants' affirmative defense of failure to state a claim

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<sup>4</sup> Defendants go on to contend that the Court's previous opinion acknowledged, and Defendants anticipate, that discovery will reveal that the factual averments underlying many of Plaintiff's theories are not true. That defense, however, is far different from the First and Second Affirmative Defenses, which allege that the Amended Complaint fails "to state facts sufficient to adequately *plead* a cause of action against Defendants" and fails "to meet the *pleading* requirements of Federal Rules of Civil Procedure 8(a) and 9(b)." (Answer at Aff. Defs. 2 & 3 (emphasis added).)

upon which relief may be granted *was not* raised in the original motion to dismiss and thus could not be later presented via an affirmative defense. Id. at \*7. The court disagreed with plaintiff's position and declined to strike the affirmative defense, noting that it had not yet had the opportunity to consider whether the RICO claim at issue was properly pled, making the defense still viable, and would not do so within the context of a motion to strike. Id. By contrast, in this case, Defendants already raised, via a comprehensive Motion to Dismiss under Rule 12(b)(6), all of the various reasons why they believed the Amended Complaint failed to state a complaint upon which relief may be granted. The Court squarely rejected these arguments, thereby requiring that the identical Affirmative Defenses be stricken.

In short, the First and Second Affirmative Defenses have been conclusively determined by the Court. As such, the Motion to Strike these affirmative defenses is granted.

## **2. Third Affirmative Defense**

Plaintiff also seeks to strike Defendants' Third Affirmative Defense. This Defense states that "Plaintiff's action is barred by 31 U.S.C. § 3730(e)(4) because it is based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administration, or Government [General] Accounting Office report, hearing, audit, or investigation, or from the news media; and Plaintiff is not an original source as that term is defined b § 3730(e)(4)(b)." Plaintiff contends that Defendants raised this precise defense in their Motion to Dismiss and the Court rejected their argument on the grounds that there was no public disclosure. Accordingly, he asserts that because the Court has already determined this issue as a matter of law, Defendants should not be entitled to re-litigate it via an Affirmative Defense.

The Court agrees in part. In their Motion to Dismiss, Defendants argued that there were

two sources of public disclosure triggering the FCA’s jurisdictional public disclosure bar: (1) Caremark’s filing of the identical PDE data report on which the audit was based directly with CMS and (2) the disclosure in discovery in the 2007 MCS-Caremark Litigation (and related efforts to amend the pleadings) of precisely the same six audit findings that Plaintiff raised in this case. With respect to the first allegation, this Court outright rejected Defendants’ argument, finding that simple disclosure of PDE reports to CMS was not equivalent to public disclosure. Spay, 2012 WL 6645537, at \*47. We went on to note that the PDE data was not even minimally available to the public until 2008 and, after that period of time, disclosure of the data was restricted to certain entities, for certain specified purposes, and “subject to various regulations to prevent improper disclosure.” Id. As this legal theory was completely foreclosed by the Court’s prior opinion, Defendants cannot re-raise it via an Affirmative Defense.<sup>5</sup>

As to the production of the Audit Report during a prior civil litigation, this Court likewise declined to find that the exchange of the Audit Report between the parties constituted a public disclosure. In doing so, we commented that the Federal Rules of Civil Procedure “made a conscious effort to shift away from the principle of making discovery materials available to the public whenever possible in favor of making them available only when ‘used’ in a court proceeding.” Id. at \*46. In turn, we remarked that both parties conceded that “the Audit Report was never actually filed with the court” or otherwise “used” in the Caremark litigation. Id. at \*45. Finally, we noted that the parties had entered into a confidentiality agreement allowing them to contest the use of the precise data contained in the Audit Report and that “an issue of fact

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<sup>5</sup> Indeed, in their Response to the Motion to Strike, Defendants expressly concede this point. (Defs.’ Resp. Opp’n Mot. Strike 4.)

remain[ed] as to whether, if the Audit Report were proposed to be ‘used,’ either party would have obtained public disclosure of the Report that would have shielded the documents from public disclosure.” Id. at \*46. Based on these findings, we held, as a matter of law, that the exchange of the Audit Report between the parties in the MCS-Caremark litigation did not constitute a public disclosure for purposes of the FCA. Id.

Defendants now contend that this latter ruling was based on a “truncated factual record” and on the acceptance of the facts in the Amended Complaint as true. (Defs.’ Resp. Opp’n Mot Strike 9.) This argument, however, is mistaken. Both parties agreed that the Audit Report was never used in the Caremark litigation, was never filed in any court proceedings, and was never disclosed to the public. Although the Court noted a factual dispute as to whether there *could* have been unprotected use of the Audit Report during the Caremark litigation, the fact remained that—according to the parties’ own concessions—there was no such “use” or filing with the Court.<sup>6</sup> Contrary to Defendants’ belief, no further discovery can change that.

In a final effort to establish that the Court’s ruling does not bar their Third Affirmative Defense, Defendants assert that this Court “acknowledge[d] that a written agency response to a FOIA [Freedom of Information Act] request would constitute a public disclosure for purposes of the FCA.” (Defs.’ Resp. Opp’n Mot. Strike 9.) They go on to argue that “facts may come out during discovery that at least some of Relator’s allegations were based upon PDE data publicly disclosed through a FOIA request.” Id. As such, Defendants claim that the Third Affirmative Defense should not be stricken.

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<sup>6</sup> Notably, the public disclosure bar of § 3730(e)(4)(A) operates only when the complaint at issue was based on public disclosures. United States ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506, 519 (3d Cir. 2007). As such, any subsequent disclosure cannot effect a bar.

This argument gives the Court some pause. Undoubtedly, the prior Memorandum recognized that a written agency response to a Freedom of Information Act request could constitute a “report” as defined in the FCA, and, in turn, could be a public disclosure. Spay, 2012 WL 6645537, at \*46. During the Motion to Dismiss phase, Defendants did not make any claim that there was any Freedom of Information Act request made for the PDE data at issue here, let alone any response by the government that would constitute a “report.” Their failure to do so at that time, however, is not fatal to their Defense. Should discovery reveal that a Freedom of Information Act for the PDE data at issue was in fact made and that the Government issued a response which publicly disclosed this PDE data, Defendants could, in theory, establish the public disclosure bar. Accordingly, the Court will allow Defendants to pursue their Third Affirmative Defense, but only on the theory that a written agency response to a Freedom of Information Act request publicly disclosed the PDE data at issue in this case.<sup>7</sup>

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<sup>7</sup> Plaintiff argues that “Defendants’ hypothetical basis for the application of the public disclosure bar falls far short of providing Relator with fair notice of the nature of the defense and hence should be stricken.” (Pl.’s Reply Br. 5.) In support of this proposition, Plaintiff cites to Dann v. Lincoln Nat’l Corp., 274 F.R.D. 139, 145–46 (E.D. Pa. 2011), wherein the court applied the Twombly/Iqbal pleading standards to affirmative defenses.

The holding of Dann, however, has been the subject of much disagreement within the Third Circuit. In Charleswell v. Chase Manhattan Bank, N.A., No. Civ.A.01-119, 2009 WL 4981730 (D.V.I. Dec. 8, 2009), the court found that Twombly and Iqbal do not apply to the pleading of affirmative defenses since Federal Rule of Civil Procedure 8(c) only requires that a party “state” their affirmative defenses. Id. at \*4. Similarly, in Fed. Trade Comm’n v. New Hope Modifications, LLC, No. Civ.A.09-1204, 2011 WL 883202 (D.N.J. Mar. 10, 2011), the court remarked that affirmative defenses are not subject to the same pleading standards as complaints. Id. at \*2–3. Finally, in Tyco Fire Prods. LP v. Vitaulic Co., 777 F. Supp. 2d 893 (E.D. Pa. 2011), the court concluded that “[a]n affirmative defense need not be plausible to survive; it must merely provide fair notice of the issue involved.” Id. at 900–01.

Without conclusively resolving this dispute, this Court errs in favor of finding that affirmative defenses need only provide fair notice to the opposing party and should not be subject to the Twombly/Iqbal standards. To that end, Defendants’ current theory of the public disclosure bar provides fair notice of the defense to Plaintiff.

### 3. Tenth and Eleventh Affirmative Defenses

In their final argument under the theory of already-litigated issues, Plaintiff moves to strike Defendants' Tenth and Eleventh Affirmative Defenses. The Tenth Affirmative Defense asserts that "Plaintiff's claims are barred because the alleged false certifications were not a condition of payment." (Answer at Aff. Def. 10.) The Eleventh Affirmative Defense states that "Plaintiff's claims are barred because the allegedly false implied certifications concern a statute or regulation that does not expressly require compliance as a condition of payment." (*Id.* at Aff. Def. 11.) Plaintiff now contends that the law of the case doctrine precludes these Defenses because such issues have already been conclusively adjudicated.

Defendants respond that "[u]nder an implied false certification theory, 'a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the basis of a plaintiff's FCA claims, it would not have paid the defendant's claims.'" (Defs.' Resp. Opp'n Mot. Strike 10 (quoting Wilkins v. United Health Grp., Inc., 659 F.3d 295, 307 (3d Cir. 2011).) To that end, Defendants contend that there are critical and disputed issues of fact relating to whether or not the accuracy of any or all of the six fields of PDE data implicated by Relator's allegations had any effect on whether CMS considered a particular claim eligible for payment. *Id.* By way of example, Defendants note that the Court acknowledged that whether incorrect prescriber identities were intentionally false or whether the government would have refused payment on the claims submitted by Defendants with false prescriber identities remains a matter for discovery.

As to Defendants' Tenth Affirmative Defense—challenging Plaintiff's express false certification theory—Defendants' argument misunderstands the Court's prior ruling. As we

noted previously, “[u]nder the ‘express false certification’ theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds.” Spay, 2012 WL 6645537, at \*15 (quotations omitted). Plaintiff, in this case, alleged that, as a condition of payment under the Part D Program, Defendants were required to certify that the PDE’s they submitted were “true, accurate, and complete,” “based upon best knowledge information and belief,” as required by 42 C.F.R. § 423.505(k)(1) and (3), yet Defendants knowingly submitted false and inaccurate Medicare Part D PDEs to Medicare in violation of the express certification. Id. at \*16. Considering Defendants’ contention in their Motion to Dismiss that the certification under this regulation was not a “condition of payment” for purposes of the FCA, the Court unequivocally held that “when properly interpreted, 42 C.F.R. § 505(k) makes proper certification of data a ‘condition of payment.’” In turn, failure of either a Part D Plan sponsor or the Sponsor’s subcontractor to submit accurate, complete, and truthful data related to payment may give rise to an FCA claim.” Id. at \*20. The Court went on to note that while 42 C.F.R. § 423.505(k)(1)’s reference to “data related to payment” includes all thirty-seven data fields on a PDE record, such data itself is not a condition of payment such that submission of these records with incomplete or inaccurate data automatically gives rise to a violation of the False Claims Act. Id. at \*20–22. Rather, as we noted, “it is the act of certifying the truth, accuracy, and completeness of these fields under § 423.505(k)(1) & (3) when such data is not actually truthful, accurate, or complete, that gives rise to a False Claims Act cause of action.” Id. at \*22. Finally, the Court concluded that a question of fact remained only as to whether the allegedly false PDE data—included in the fields of Maximum Allowable Cost pricing and Physician Identification

Numbers—were actually false or whether CMS would have actually paid out on these claims despite the falsity in their reporting. Id. at \*22–26.

Ultimately, at the core of the Court’s decision was an explicit legal conclusion that:

[A]s a condition for receiving payment, a Part D sponsor must certify the accuracy, completeness, and truthfulness of all data, including claims data, related to the requested payment from the government. When that claims data is generated by a subcontractor of a Part D Sponsor, such as a PBM, the subcontractor must similarly certify, as a condition of payment, the truthfulness, accuracy, and completeness of the data. . . . Section 423.505(k)(3) was designed precisely to make subcontractor’s certification of the truthfulness, accuracy, and completeness of claims data a condition of payment.

Id. at \*18. Thus, to the extent the Tenth Affirmative Defense contends that “Plaintiff’s claims are barred because the alleged false certifications were not a condition of payment,” this Affirmative Defense must be stricken as already thoroughly considered and conclusively adjudicated by the Court.

Defendants’ Eleventh Affirmative Defense, however, merits a different conclusion. The Third Circuit has recognized that there are two types of false certifications, express and implied. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011). Where the Tenth Affirmative Defense challenged only Plaintiff’s express false certification theory, the Eleventh Affirmative Defense is geared towards any potential implied false certification theory raised by the Amended Complaint. Under this theory, an FCA claim arises “when a claimant seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment.” Id. at \*15. The Third Circuit has cautioned, however, that this theory must not be applied expansively and that “under this theory a plaintiff must show that if the Government had been aware of the defendant’s violations of the Medicare laws and

regulations that are the bases of a plaintiff’s FCA claims, it would not have paid the defendant’s claims.” Id.

In our prior Opinion, this Court unequivocally found that Defendants’ alleged failure to honestly certify the truthfulness, accuracy, and completeness of the PDE data submitted to CMS—specifically the Maximum Allowable Cost (“MAC”) pricing and the Physician Identification Numbers—stated an express false certification violation of the FCA. The Court went on to remark that an issue of fact remained as to whether the MAC pricing and physician identification number field were actually false and whether, if CMS knew that Defendants had improperly certified their accuracy, it would have still paid out on the claims. In other words, the Court did not conclusively determine that if the Government had been aware of the defendant’s violation of the Medicare laws and regulations that are the bases of plaintiff’s FCA claims, it would not have paid Defendants’ claims. As this is the precise issue raised by the Eleventh Affirmative Defense, the Court declines to strike it.

**B. Defenses that Are Unavailable and/or Inapplicable as a Matter of Law**

In his second broad challenge to Defendants’ Affirmative Defenses, Plaintiff asserts that at least four of the Defenses are insufficient as a matter of law because they either are improper affirmative theories or are inapplicable against Relator/United States in this case. Plaintiff goes on to contend that, if permitted to stand, these defenses will unnecessarily complicate this litigation and result in the parties and Court expending time addressing issues inapplicable to this case. The Court considers each Affirmative Defense individually.

**1. Twelfth Affirmative Defense**

The Twelfth Affirmative Defense states, “Plaintiff purposely and unreasonably delayed in

making known to Defendants the allegations contained in the Amended Complaint and attempting to assert those claims. This unreasonable delay has prejudiced Defendants in that evidence bearing on Plaintiff's claims may have been lost. Plaintiff's causes of action are therefore barred in whole or in part by the doctrine of laches, estoppel, waiver, ratification, and/or unclean hands.”<sup>8</sup> (Answer at Aff. Def. 12.)

**a. Laches**

“Laches bars an action from proceeding if there was (1) an inexcusable delay in bringing suit, and (2) material prejudice to the defendant as a result of the delay.” Marshak v. Treadwell, \_\_\_ F.3d \_\_\_, Nos. 08-1771, 08-1836, 08-1837, 2009 WL 1886153, at \*13 n.14 (3d Cir. July 2, 2009) (citations omitted). “It is well established,” however, “that the United States is not subject to the defense of laches in enforcing its rights.”<sup>9</sup> United States v. St. John's Gen. Hosp., 875 F.2d 1064, 1071 (3d Cir. 1989) (citing United States v. Summerlin, 310 U.S. 414, 416 (1940)); see also United States v. Zarra, 810 F. Supp. 2d 758, 769 (W.D. Pa. 2011) (striking affirmative defense of laches because it is well established that the United States is not subject to the defense of laches in enforcing its rights), aff'd, 477 F. App'x 859 (3d Cir. 2012); U.S. ex rel. Head v. Kane Co., 668 F. Supp. 2d 146, 150–51 (D.D.C. 2009) (noting that no rule is better established than that the United States are not bound by limitations or barred by laches where they are asserting a public right and granting motion to strike affirmative defense of laches in an FCA

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<sup>8</sup> Defendants have withdrawn their defense of unclean hands.

<sup>9</sup> Notably, “although the United States is not a ‘party’ to a qui tam suit unless it intervenes, it is nonetheless a real party in interest—which is to say that its financial interests are at stake.” United States ex rel. Liotine v. CDW Govt., Inc., No. Civ.A.05-33, 2012 WL 2807040, at \*15 (S.D. Ill. July 10, 2012) (quoting United States ex rel. Lusby v. Rolls-Royce Corp., 570 F.3d 849, 852 (7th Cir. 2009)).

suit); United States v. Thurston, 346 F. Supp. 2d 215, 219 (D. Me. 2004) (“A virtually unbroken line of authority . . . holds that a private defendant cannot assert laches against the government.”) (quoting United States v. Hughes House Nursing Home, Inc., 710 F.2d 891, 895 (1st Cir. 1983)); United States ex rel. Jordan v. Northrop Grumman Corp., No. Civ.A.95-2985, 2002 U.S. Dist. LEXIS 26622, at \*18 (C.D. Cal. Aug. 5, 2002) (striking affirmative defense of laches because “it is clear that the government is not subject to a defense of laches when enforcing its rights.”) (internal quotation marks omitted). The Third Circuit has recently reaffirmed this principle, finding that the United States is not subject to the defense of laches in enforcing its rights. United States v. Tuerk, No. Civ.A.07-2962, 2009 WL 612497, at \*1 (3d Cir. Mar. 11, 2009); see also Alvarado v. Attorney Gen. of U.S., 401 F. App’x 63, 676 (3d Cir. 2010) (acknowledging that despite extreme governmental delay, any defense of laches against the government must “surely fail”).

In the context of an FCA claim, there are two other bars to invoking the equitable defense of laches. “First, laches generally does not apply when a claim is brought at law, that is only for monetary damages.” United States ex rel. Kusner v. Osteopathic Med. Ctr. of Phila., No. Civ.A.88-9753, 1996 WL 287259, at \*6 (E.D. Pa. May 30, 1996). Because the False Claims Act does not provide for injunctive or other equitable relief and the Amended Complaint in this action seeks only monetary damages, laches could not apply. Id. Second, laches does not usually apply when a claim is subject to a statute of limitations. Id. Because the False Claims Act provides a six year statute of limitations, 31 U.S.C. § 3731(b), laches cannot operate to bar an otherwise timely claim under the FCA. Id.

Defendants’ sole applicable case in support of their argument that laches is a potential

affirmative defense to an FCA claim is a matter arising out of the District of New Jersey. In United States ex rel. Monahan v. Robert Wood Johnson Univ. Hosp., No. Civ.A.02-5702, 2009 WL 4576097 (D.N.J. Dec. 1, 2009), the court, via a rather ambiguous and cursory ruling, declined to dismiss an affirmative defense of laches in an FCA case on the ground that “[t]here appears to be persuasive authority holding that, at least in limited circumstances that may possibly be present here, laches may be applied successfully against the Government.” Id. at \*7. That court, however, relied only on cases from the Second and Seventh Circuit and gave relatively short shrift to the issue. Id. at \*6. Given the lack of any definitive legal analysis in that case, the Court disregards that ruling as mere *dicta*, particularly in light of the wealth of other jurisprudence—including a recent Third Circuit case—holding that the doctrine of laches is plainly unavailable against the United States in its enforcement of its rights.<sup>10</sup>

In short, the Court finds that the law is well-settled that the equitable doctrine of laches may not be raised against the United States in the enforcement of its rights under the FCA, regardless of whether Defendants could prove the substantive elements of that defense. For that reason, this portion of the Twelfth Affirmative Defense must be stricken.

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<sup>10</sup> Defendants cite to Dole v. Local 427, Int'l Union of Elec., Radio, and Mach. Workers, 894 F.2d 607 (3d Cir. 1990), wherein the Third Circuit “le[ft] open the question of whether laches can apply as a defense against the Government suing to protect such public interests.” Id. at 616. This case is of no import in light of the Third Circuit’s more recent pronouncement in United States v. Tuerk that the United States is not subject to the defense of laches in enforcing its rights. 317 F. App’x at 253.

Moreover, although Defendants cursorily mention NJ v. RRI Energy Mid-Atl. Power Holdings, LLC, No. Civ.A.07-5298, 2010 WL 2958777 (E.D. Pa. Sept. 30, 2010), the court in that case declined to strike the affirmative defense of laches because it was unclear whether a plaintiff in a citizen-suit under the Clean Air Act could invoke the same protection as the government. Id. at \*10. This case, however, involves the FCA, not the Clean Air Act.

**b. Estoppel**

Plaintiff next argues that Defendants' estoppel defense is clearly foreclosed by controlling jurisprudence. On this point, the Court must disagree. The Third Circuit squarely confronted this issue in Monongahela Valley Hosp., Inc. v. Sullivan, 945 F.2d 576, 588 (3d Cir. 1991), wherein it cited to the United States Supreme Court's holding in Office of Personnel Mgmt. v. Richmond, 496 U.S. 414, 434 (1990), which stated:

Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address. As for monetary claims, it is enough to say that this Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds. In this context, there can be no estoppel for courts cannot estop the Constitution.

Monongahela, 945 F.2d at 588 (quoting Richmond, 496 U.S. at 434). Relying on this pronouncement, the Third Circuit held that absent extreme circumstances, a party cannot invoke equitable estoppel against the government in asserting certain monetary claims. Monongahela, 945 F.2d at 589. The Third Circuit, however, then went on to note that even assuming Richmond did not completely foreclose an estoppel defense against the government, the party in that case had failed to meet the requirements for invoking equitable estoppel. Id.

"District courts in this circuit have either applied Richmond outright to applicable equitable estoppel claims against the government or have followed the approach of the court of appeals in Monongahela Valley Hospital and determined whether a party could establish equitable estoppel against the government subject to the test set forth [by the Third Circuit] in Asmar."<sup>11</sup> Davis v. United States, No. Civ.A.05-1609, 2007 WL 951442, at \*13 (W.D. Pa. Mar.

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<sup>11</sup> Defendants cite United States v. Asmar, 827 F.2d 907, 912 (3d Cir. 1987) for proposition that the Third Circuit "is one of the majority of circuits which recognize the validity of an estoppel defense against government parties." Notably, however, Asmar predated

26, 2007) (citing cases). This Court’s reading of the language in Richmond and Monongahela reveals that there is no such outright prohibition on the application of equitable estoppel against the government. Rather, these cases recognize circumstances—albeit extreme ones—in which a party may invoke this defense against the government. See Id. at \*11 (“The United States Court of Appeals for the Third Circuit recognizes that Richmond left open the possibility that some type of affirmative misconduct might give rise to estoppel against the government (citing SIU de Puerto Rico v. Virgin Islands Port Auth., 42 F.3d 801, 803–04 (3d Cir. 1994) (“The government cannot be estopped from denying the validity of an agreement unless it engaged in affirmative misconduct as opposed to mere omission or negligent failure.”)).

As set forth previously, it is well-established that “a court should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’ . . . The underpinning of this principle rests on a concern that a court should restrain from evaluating the merits of a defense where, as here, the factual background for a case is largely undeveloped.” Cipollone v. Liggett Grp., Inc., 789 F.2d 181, 188 (3d Cir. 1986) (internal citations omitted); see also Nupro Indus. Corp. v. Lexington Ins. Co., No. Civ.A.08-4809, 2010 WL 2553698, at \*4 (E.D. Pa. June 21, 2010) (holding that a court should only strike an affirmative defense when “it is clearly apparent that the defense cannot succeed under any circumstances as a matter of law.”); FTC v. Hope Now Modifications, LLC, No. Civ.A.09-1204, 2011 WL 883202, at \*4 (D.N.J. Mar. 10, 2011) (“An affirmative defense can be stricken only if the defense asserted could not possibly prevent recovery under any pleaded or inferable set of facts.”) (quotations omitted). As

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Richmond by more than two years. As such, the validity of its ruling remains uncertain in the wake of Richmond.

discovery has yet to commence in this case and as there are a set of inferrable circumstances under which Defendants could potentially succeed, the Court must deny Plaintiff's Motion as to this Defense.<sup>12</sup>

**c. Waiver and Ratification**

Defendants' Twelfth Affirmative Defense also claims that Plaintiff's causes of action are barred by the doctrines of waiver and ratification because Plaintiff purposely delayed in making known to Defendants the allegations in the Amended Complaint. Plaintiff now asks that the Court strike this Affirmative Defense as both devoid of factual or legal support and wholly inapplicable to the case.

Congress has vested the Attorney General as the governmental entity with the authority to bring civil actions under the FCA. 31 U.S.C. § 3730; see also 28 U.S.C. § 516 ("Except as otherwise provided by law, the conduct of litigation in which the United States, an agency, or officer thereof is a party, or is interested, and securing evidence therefor, is reserved to officers of the Department of Justice, under the direction of the Attorney General."); Martin J. Simko Constr. v. United States, 852 F.2d 540, 548 (Fed. Cir. 1988) ("Congress could not have stated more clearly its intent to give the Attorney General specific authority to 'administer, settle, or determine' claims or disputes under the False Claims Act."). "Violations of the FCA, therefore, may only be waived by the Department of Justice, and the unauthorized statements of United States agents may not serve to waive the Government's claims." Monahan, 2009 WL 4576097, at \*7 (citing Sappiest v. Omaha Prop. & Caves., 404 F.3d 805, 809 (3d Cir. 2005)). As such,

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<sup>12</sup> Plaintiff contends that Defendants have not met the requirements for invoking the estoppel doctrine against the United States. This inquiry, however, is inappropriately considered on a Motion to Strike filed prior to the commencement of discovery.

where a party alleges conduct by the Attorney General that could be construed as waiver of the Government's FCA claims, and where discovery has failed to commence or remains in its early stages, this defense should be allowed to proceed. Id.; see also United States v. Ctr. for Diagnostic Imaging, Inc., No. Civ.A.05-058, 2011 WL 6300174, at \*3 (W.D. Wash. Dec. 6, 2011) (holding that waiver defense asserted in light of litigation history of case and accord and satisfaction on account of a settlement agreement previously reached with the United States should not be stricken and was "better dealt with after the parties have had the benefit of discovery"); United States ex rel. Roby v. The Boeing Co., 100 F. Supp. 2d 619, 643, 646 (S.D. Oh. 2000) (finding that government knowledge and disregard of defendant's alleged misconduct could constitute valid waiver/ratification defense that should not be stricken); Jordan, 2002 U.S. Dist. LEXIS 26622, at \*19–20 (declining to strike waiver and ratification defenses on the ground that courts consider the fact that the government knew of the defendant's mistakes and limitations and that the government knew of the falsity of certain statements by the defendant in determining whether a defendant possessed the requisite scienter to violate the FCA).

Had Defendants in this case alleged that the government waived and/or ratified Defendants' alleged misconduct through their own actions or knowledge, the Court would have allowed this defense, however tenuous, to proceed through discovery. The Twelfth Affirmative Defense, however, does not allege any action or knowledge by the *government*, but rather by the *Plaintiff*. To be clear, the Defense states:

*Plaintiff purposefully and unreasonably delayed in making known to Defendants the allegations contained in the Amended Complaint and attempting to assert those claims. This unreasonable delay has prejudiced Defendants in that evidence bearing on Plaintiff's claims may have been lost. Plaintiff's causes of action are therefore barred in whole or in part by the doctrines of laches, estoppel, waiver, ratification,*

and/or unclean hands.

(Answer at Aff. Def. 12 (emphasis added).) Thus, unlike the foregoing cases that allowed waiver and ratification defenses to proceed, Defendants do not allege any government knowledge of the falsity of their statements or actions. Because violations of the FCA may only be waived by the Department of Justice, whether Plaintiff purposefully and unreasonably delayed or knew of Defendants' alleged misconduct is irrelevant. In turn, the Court strikes this portion of the Twelfth Affirmative Defense.<sup>13</sup>

## 2. Twenty-Third Affirmative Defense

Defendants' Twenty-Third Affirmative Defense asserts that "Plaintiff's claims are barred, in whole or in part by the learned intermediary doctrine." (Answer at Aff. Def. 23.) Under the learned intermediary doctrine, as applied in Pennsylvania, drug manufacturers are relieved from liability in tort actions if adequate warning is given to the physician." Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374, 378 (Pa. 1987). The rationale behind this doctrine is simple: "[i]n the dispensing of prescription drugs, the physician is required to act as a learned intermediary between the manufacturer and patient because of the complexity of medicines and the doctor's medical knowledge." Ferrara v. Berlex Labs., Inc., 732 F. Supp. 552, 555 (E.D. Pa.), aff'd, 914 F.2d 242 (3d Cir. 1990). This doctrine applies "[i]n cases involving the failure to warn of risks associated with prescription drugs." Cochran v. Wyeth, Inc., 3 A.3d 673, 676 (Pa. Super.

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<sup>13</sup> To the extent Defendants intend to assert that they did not act with the requisite intent because the government had knowledge of and/or ratified the alleged violation, this defense is encompassed by the Thirteenth Affirmative Defense, which states that "Plaintiff's claims are barred because the United States' knowledge of the alleged conduct in the Amended Complaint and/or acquiescence of such conduct defeats the elements of falsity, scienter, materiality, and causation, and precludes all damages in this action." (Answer at Aff. Def. 13.)

Ct. 2010), appeal denied 20 A.3d 1209 (Pa. 2011).

Defendants now note that the Amended Complaint makes numerous inflammatory statements to the effect that Defendants' alleged failure to perform Drug Utilization Review ("DUR") for gender contraindications, expired NDC codes, prior authorizations, and drugs dispensed over formulary limitations was "dangerous" to the Medicare beneficiary. They go on to assert that, "[b]y these allegations, Relator plainly suggests that Caremark's liability in this FCA case somehow is related to a duty to protect beneficiaries from physical dangers Relator contends are created by the alleged failure to perform DUR." (Defs.' Resp. Opp'n Mot. Strike 16.)

Defendants, however, cite to no case that has applied the learned intermediary doctrine to bar the United States in an FCA case. Indeed, this case involves only allegations that Defendants failed to perform their statutory and contractual allegations as a PBM and Part D sponsor, ultimately resulting in the submission of false claims for payment. The only victim here is the government—not some unknowing consumer of the drugs dispensed by Defendants. Before any "learned intermediary" would have had an opportunity to warn a consumer about the drugs dispensed by Defendants, the alleged FCA violation would already have been committed and the harm inflicted upon the government. Accordingly, the learned intermediary doctrine would have no logical purpose or practical application to such a case. Given that there is no set of inferrable facts under which Defendants could succeed on this defense, the Court grants Plaintiff's Motion to Strike.<sup>14</sup>

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<sup>14</sup> Defendants cite a litany of allegations from the Amended Complaint wherein Plaintiff alleged that the regulations and laws which Defendants allegedly disregarded were designed to protect patients from harm resulting from the use of unsafe or inappropriate drugs. (Defs.' Resp.

### 3. Twenty-Eighth Affirmative Defense

Defendants' Twenty-Eighth Affirmative Defense states that, "This Court lacks subject matter jurisdiction based on the doctrines of exclusive and primary jurisdiction and failure to exhaust administrative remedies." (Answer at Aff. Def. 28.) Plaintiff now asserts that the Court should strike this Affirmative Defense because subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1331 and 1345, as this is an action on behalf of the United States and arises under the laws of the United States to redress violations of the federal False Claims Act. Plaintiff goes on to assert that the United States is not required to exhaust any administrative remedies before pursuing a defendant under the FCA for that defendant's submission of a materially false claim for payment.

Defendants offer several responses, none of which this Court finds convincing. First, although they concede that jurisdiction for cases arising under the FCA is proper in the federal courts under 31 U.S.C. § 3730, they assert that they are asserting the Twenty-Eighth Affirmative Defense to protect their right to challenge this Court's jurisdiction under the public disclosure bar. However, such a defense, which directly asserts lack of jurisdiction based on the public disclosure bar and which was previously upheld by the Court, is redundant of Defendants' Third Affirmative Defense. "Rule 12(f) permits the court to 'order stricken from any pleading any . . . redundant . . . matter.' Redundant matter 'consists of allegations that constitute a needless repetition of other averments.'" Environ Prods., Inc. v. Total Containment, Inc., 951 F. Supp. 57,

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Opp'n Mot. Strike 16 n.13.) The Court reads these allegations as nothing more than context for the FCA claim and does not interpret them to infer that Defendants are liable to consumers of the drugs under a failure to warn or strict liability theory. Nor do they appear to be inflammatory in any sense. Thus, the Court declines Defendants' request to strike such allegations under Federal Rule of Civil Procedure 12(f).

59 (E.D. Pa. 1996) (quotations omitted). Thus, to the extent Defendants' Twenty-Eighth Affirmative Defense relies on the same public disclosure bar set forth in the Third Affirmative Defense, it is stricken as redundant.

Second, Defendant argues that “[i]t is entirely appropriate at this stage of the litigation for Caremark to assert the doctrines of primary jurisdiction and failure to exhaust administrative remedies as an affirmative defense based on the CMS-regulated reconciliation process by which CMS adjusts payments to reflect PDE submissions.” (Defs.' Resp. Opp'n Mot Strike 17.) Specifically, Defendants contend that under CMS's administrative procedures, both CMS and a Part D Plan Sponsor (in this case, MCS) have the ability to reopen the reconciliation process to correct or delete PDEs. A PBM (such as Caremark), however, does not have the ability to do so. Because there are no allegations that either MCS or CMS invoked that administrative process to correct or delete the PDE elements at issue, notwithstanding MCS's knowledge of the audit findings and the presence of obviously incorrect numbers in the PDE submissions, Defendants argue that CMS retains primary jurisdiction over this matter.

The Court finds no legal merit to this argument. The sole document on which Defendants rely—a report from the Department of Health and Human Services Office of Inspector General, OEI-02-08-00460 entitled “Medicare Part D Reconciliation Payments for 2006 and 2007”—says nothing about any requirement to exhaust administrative remedies prior to bringing an FCA claim. Rather, it simply states as follows:

CMS *may* reopen and revise the reconciliation payment amounts at its own initiative or at the request of a Part D sponsor. It *may* do so for any reason within 12 months from the date of the notice of final determination to the sponsor or for “good cause” within 4 years of the determination. Although *sponsors may request a reopening, these requests are granted at the discretion of CMS.* In addition, a Part D sponsor

may appeal its reconciliation payment amount if it believes that CMS did not apply its payment methodology correctly.

<http://oig.hhs.gov/oei/reports/oei-02-08-00460.pdf> (emphasis added). The language contained in this document is, at best, permissive, not mandatory. Likewise, Defendants have not cited—and this Court's own research cannot unearth—any case or statutory provision imposing any exhaustion of administrative remedies requirement on plaintiffs bringing FCA claims, either in the Medicare context or any other context. Finally, even assuming *arguendo* that Defendants are correct in their contention that jurisdiction remained with CMS while the prescribed administrative procedures were available, the plain language of the foregoing report makes clear that reconciliation payments may only be reopened within four years of the determination. The events giving rise to this case occurred more than four years ago, meaning that there no longer exists an avenue for administrative review of the payments made by CMS.

Ultimately, as noted by Plaintiff, the FCA is clearly the appropriate means to bring enforcement actions against Part D Sponsors and their subcontractors who submit false claims data to CMS. (CMS Prescription Drug Benefit Manual, Chapter 9, § 801.) According to CMS's own Prescription Drug Benefit Manual, “[t]he False Claims Act is enforced against any individual/entity that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government.” (*Id.*) Nothing within that Manual suggests that any administrative procedures must, or even should be followed prior to seeking relief under the False Claims Act. Accordingly, the Court strikes this Affirmative Defense.

### **C. Affirmative Defenses that Are Facially Improper**

Plaintiff's final challenge asserts that the Fourth, Fifth, Sixth, Seventh, Eighth, Ninth,

Fifteenth, Sixteenth, Seventeenth, and Eighteenth Affirmative Defenses are nothing more than mere denials of liability. Specifically, these Defenses state as follows:

Fourth Affirmative Defense - The claims asserted in the Amended Complaint are barred, in whole or in part, because Defendants acted at all relevant times in good faith and not with any improper or illegal purpose, intent or knowledge. Each and every act or omission that Defendants are alleged to have undertaken or failed to have undertaken in the Amended Complaint was done or omitted in good faith and not with any improper or illegal purpose, intent or knowledge, and in conformity with all applicable federal and state statutes, and all applicable rules and CMS guidance promulgated thereunder.

Fifth Affirmative Defense - Plaintiff's claims are barred because Defendants did not act "knowingly" as that term is defined in 31 U.S.C. § 3729(b)(1).

Sixth Affirmative Defense - Plaintiff's claims are barred because the records or statements allegedly made, used, or caused to be made or used by Defendants were not false.

Seventh Affirmative Defense - Plaintiff's claims are barred because the records or statements allegedly made, used, or caused to be made or used by Defendants were not false.

Eighth Affirmative Defense - Plaintiff's claims are barred because there was no false claim.

Ninth Affirmative Defense - Plaintiff's claims are barred because Defendants made no express or implied false certification.

Fifteenth Affirmative Defense - Plaintiff's claims are barred because Defendants' conduct was not material to any alleged payment or receipt of money or property in connection with any alleged false or fraudulent claim.

Sixteenth Affirmative Defense - Plaintiff is not entitled to the damages or remedies he seeks.

Seventeenth Affirmative Defense - Plaintiff's claims are barred because the United States has not suffered, and it will not suffer, any damages or injury to a legally protected or cognizable interest by reason of the conduct of Defendants.

Eighteenth Affirmative Defense - The United States did not rely on the alleged statements, actions, or inaction of Defendants complained of in the Amended

Complaint, and Defendants' statements, actions, or inaction otherwise were not the proximate cause or cause in fact of any injury to or alleged loss by the United States.

(Answer at Aff. Defs. 4, 5, 6, 7, 8, 9, 15, 16, 17.) Plaintiff argues that under pertinent jurisprudence, "affirmative defenses" that are essentially nothing more than denials of liability of elements of a plaintiff's cause of action may be stricken as redundant. In this case, the foregoing Defenses are precisely that—mere denials of liability. As such, according to Plaintiff, they do not fit within the definition of an affirmative defense and must be stricken.

The Third Circuit has defined an affirmative defense as follows:

A matter asserted by defendant which, assuming the complaint to be true, constitutes a defense to it. A response to a plaintiff's claim which attacks the plaintiff's [legal] right to bring an action, as opposed to attacking the truth of [the] claim.

In re Sterten, 546 F.3d 278, 284 n.9 (3d Cir. 2008) (referencing Black's Law Dictionary 60 (6<sup>th</sup> ed. 1990) (internal quotations and emphasis omitted)). Some courts within the Third Circuit have stricken as improper affirmative defenses that are mere denials of liability or attacks on the truth of the claim, as opposed to legal defense. See, e.g., Monahan, 2009 WL 4576097, at \*5–6 (striking as improper an affirmative defense that "the complaint fails to allege any materially false statement" because it merely attacked the truth of the plaintiff's allegations and was not properly pled as an affirmative defense); Modern Creative Servs., Inc. v. Dell Inc., No. Civ.A.08-3891, 2008 WL 305747, at \*2 (D.N.J. Jan. 28, 2008) (striking as facially improper affirmative defenses that merely denied the truth of the allegations in the amended complaint).

Notwithstanding these rulings, this Court declines to strike Defendants' Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Fifteenth, Sixteenth, Seventeenth, and Eighteenth Affirmative Defenses. By all accounts, these defenses are not technically "affirmative defenses" as defined

by the Third Circuit, in that they dispute the veracity of the allegations in the Amended Complaint. Nonetheless, the Third Circuit has cautioned that courts “should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’” Cipollone, 789 F.2d at 188. In light of this standard, “motions to strike are not favored and will typically be denied ‘unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues in the case.’” AMEC Civil, LLC v. DMJM Harris, Inc., No. Civ.A.06-64, 2007 WL 433328, at \*4 (D.N.J. Feb. 6, 2007) (quotations omitted).

Given this legal backdrop, the Court finds no purpose served in eliminating these Defenses. First, despite retaining the burden in a motion to strike, Plaintiff offers little practical reason why such Defenses must be stricken, other than arguing that they are not affirmative defenses. Second, while Defendants were not required to include these Affirmative Defenses in order to preserve their arguments, the arguments raised are nevertheless relevant to the issues at hand. Indeed, by asserting such defenses here, Defendants give notice of the grounds on which they intend to defend the FCA claim and avoid later motions that they waived these defenses. Finally, retaining these allegations as Affirmative Defenses will not, in any way, exacerbate the discovery burdens on the parties or cause additional time and litigation expense since discovery will be precisely focused on these same issues. In other words, “the policy interests that support a motion to strike—the elimination of unnecessary expensive discovery—[are not] sufficiently implicated by the remaining affirmative defenses to strike them on the basis of plaintiff’s limited discussion of their legal sufficiency.” F.D.I.C. v. White, 828 F. Supp. 304, 314 (D.N.J. 1993). In short, as Plaintiff has not provided the Court with sufficient basis to strike these defenses and

as motions to strike are generally disfavored, the Court denies Plaintiff's Motion as to these Affirmative Defenses.

#### **IV. CONCLUSION**

In light of the foregoing, the Court will grant Plaintiff's Motion in part and deny it in part. First, as to Defendants' First, Second, and Tenth Affirmative Defenses, Plaintiff's Motion is granted and these Defenses are stricken as previously adjudicated by the Court. As to the Third Affirmative Defense, Plaintiff's Motion is denied, but Defendants shall only be allowed to proceed on this Defense under the theory that there was a written agency response to a Freedom of Information Act request that publicly disclosed the PDE data at issue. Plaintiff's Motion as to the Eleventh Affirmative Defense is also denied in that this Defense could succeed under an inferrable set of facts. With respect to the Twelfth Affirmative Defense, Plaintiff's Motion is granted to the extent this Defense challenges the Amended Complaint on grounds of laches, unclean hands, waiver, and ratification, but denied to the extent it raises the defense of estoppel. The Twenty-Fifth Affirmative Defense is stricken as voluntarily withdrawn by Defendants, and the Twenty-Third and Twenty-Eighth Affirmative Defenses are stricken as invalid legal theories. Finally, Plaintiff's Motion is denied to the extent it seeks to strike the Fourth, Fifth, Sixth, Seventh, Eighth, Ninth, Fifteenth, Sixteenth, Seventeenth, and Eighteenth Affirmative Defenses. An appropriate Order follows.